UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen S. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Bartlett's motion to exclude or limit testimony by three former FDA officials as fact witnesses (document no. 168) is granted in part.

1. FDA regulations, policy, or procedure

Insofar as Mutual intends for those witnesses to testify about FDA regulations, policy, or procedure on the issue of whether a generic drug manufacturer has the ability or responsibility to strengthen a generic drug's safety warning, they are expert witnesses for whom Mutual failed to make the disclosures required by Fed. R. Civ. P. 26(a)(2). Moreover, such testimony is unfairly prejudicial for the reasons discussed in this court's recent ruling on the parties' expert motions. See Bartlett v. Mut. Pharm. Co., 2010 DNH 123, at 5-9; Fed. R. Evid. 403. Bartlett's request to exclude such testimony is therefore granted.

2. Hypothetical FDA action

Insofar as Mutual intends for the witnesses to testify about what the FDA hypothetically would have done in response to a generic drug manufacturer's attempt to strengthen a generic drug's safety warning, such testimony is speculative and therefore also inadmissible. See Bartlett, 2010 DNH 123, at 7, 34 (prohibiting both parties from offering expert testimony to that effect).

3. Personal beliefs and opinions

Insofar as Mutual intends for the witnesses to offer their personal beliefs or opinions about generic drug labeling, such testimony is not relevant, see Fed. R. Evid. 401, 402, and would not be "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue," see Fed. R. Evid. 701. The same is true of any testimony about the beliefs or statements of other FDA officials. Moreover, testimony about others' beliefs is speculative, see Bartlett, 2010 DNH 123, at 7, and testimony about others' statements is hearsay, see Fed. R. Evid. 801(c). Bartlett's request to exclude such testimony is also granted.

4. Industry practice

To the extent that they have personal knowledge, however, the witnesses may testify about the FDA's actual practice in past

cases (if any) where a generic drug manufacturer has attempted to strengthen a generic drug's label, or they may testify that they have no personal knowledge of any such attempts being made during their time at the FDA (which is what their deposition testimony suggests). Such testimony is relevant and admissible as evidence of industry practice. See Bartlett, 2010 DNH 123, at 8; Fed. R. Evid. 401, 402.

5. Robert Pollock

Mutual intends to call former FDA official Robert Pollock on the issue of FDA policies and practices, primarily pertaining to drug labeling. Bartlett seeks to exclude Pollock from testifying because he failed to produce a citizen's petition that he recently prepared for Mutual seeking the FDA's permission to manufacture and sell Sulindac in capsule form (as opposed to tablets). Bartlett argues that the petition should have been produced pursuant to this court's order, dated September 25, 2009, that "the witnesses produce all expert designations, reports, depositions, and trial transcripts" at least 7 days before their depositions. But the petition is not, as Bartlett suggests, a "report" within the meaning of Fed. R. Civ. P. 26(a)(2)(B), which is clearly what this court's ruling meant. Bartlett's request to exclude Pollack from testifying on this basis is denied.

Any other objections to these witnesses' testimony will be considered at trial, if Mutual calls them to testify.

SO ORDERED.

/s/Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 22, 2010

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